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EXAMINER
NELSON, A

ART UNIT	PAPER NUMBER
1649	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/805,813

Applicant(s)

Ichiro Mitsuhashi, et al.

Examiner

Amy Nelson

Group Art Unit

1649



☒ Responsive to communication(s) filed on Jul 6, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-3, 5-13, 15, 16, and 18-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for claims limited to a recombinant gene, expression cassette and expression vector comprising the sarcotoxin 1a gene, and plants transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the last Official action mailed 3/31/98. Applicant's arguments filed 7/6/98 have been fully considered but they are not persuasive.

Applicant asserts that Claims 14, and 16-17 are directed to the sarcotoxin 1a gene, and hence should not be included in the rejection. Claims 4, 14 and 17 have been omitted from the rejection as they are specifically directed to the sarcotoxin 1a gene. However, Claim 16 is drawn broadly to a gene encoding an antibacterial peptide from a Diptera insect, and therefore Claim 16 is included in the rejection.

Applicant asserts that routine screening could be used to identify other genes which fall within the scope of the claims, and Applicant provides evidence that other anti-microbial genes have been identified that could confer anti-fungal properties on plants (response, p. 4-5).

Examiner responds that although many genes are known in the literature that encode polypeptides

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with anti-microbial properties, the effect of expression of these genes in transgenic plants is highly unpredictable. Without empirical evidence indicating which genes can be used in the claimed invention of conferring resistance to pathogenic fungi in plants, undue trial and error experimentation would be required to screen through the myriad of potential genes with anti-microbial properties, operably linked to a variety of different regulatory sequences, and the vast number of transgenic plants, to identify those transformed plants that have an anti-fungal phenotype.

Applicant further asserts that the key word is “undue” and not “experimentation” in determining whether or not the claims are enabled (response, p. 5). Examiner responds that although a certain amount of experimentation is allowed, the instant specification does not provide sufficient guidance to practice the claimed invention without undue trial and error experimentation. Given the unpredictability in the art as discussed in the previous office action, and the limited guidance provided by Applicant, undue trial and error experimentation would be required to determine how else to make transgenic plants with resistance to pathogenic fungi other than by transformation with the sarcotoxin 1a gene.

Finally, Applicant states that the Examiner has only listed the factors to be considered in assessment of enablement and has not applied the factors to the pending claims (response, p. 6). Examiner responds that in the Official action mailed 3/31/98, Examiner has reviewed the state of the art and the unpredictability of the art of producing transgenic plants with a defined phenotype, the guidance provided by Applicant in the instant specification including the working examples,

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and the breadth of the claims to conclude that undue trial and error experimentation would be required to practice the invention throughout the scope of the claims, and therefore the invention is not enabled for the broad scope.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, lines 2-3, "atacin, lysozyme, cecropin" is indefinite because it is unclear whether alternative language is intended. It is recommended that before "cecropin" --and-- be inserted.

At Claim 5, line 6, and Claim 11, line 1, "resistant" should be changed to --resistance-- to be consistent with Claim 12, line 6.

At Claim 5, line 6, "linked to" should be changed to --operably linked to-- to clarify how the two gene elements are linked.

At Claim 6, line 3, "a hinge region of a tobacco chitinase" should be changed to --a hinge region of a tobacco chitinase gene-- because a portion of a gene, not an enzyme, is used.

At Claim 9, line 2, "derived from" should be changed to --from-- because it is not known what it intended by "derived."

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At Claim 10, line 1, “the expression vector” lacks proper antecedent basis because Claim 9 is directed to the alternative of Claim 5 directed to an expression cassette, not an expression vector. It is recommended that Claim 10 be changed to depend from Claim 5.

At Claim 12, lines 3-4, “a hinge region of tobacco chitinase” should be changed to --a hinge region of a tobacco chitinase gene-- because a portion of a gene, not an enzyme, is used. Also, hinge regions are present on many different tobacco chitinase genes.

At Claim 13, the names of the organisms should be italicized.

At Claim 14, line 2, “derived from” should be changed to --from-- because it is not known what is intended by “derived.”

At Claim 15, “in which” is indefinite and should be changed to --comprising--.

At Claim 15, line 2, “is bound to” is indefinite and should be changed to the standard terminology of --operably linked to--.

At Claim 16, line 3, “derived from” should be changed to --from-- because it is not known what it intended by “derived.”

At Claim 17, line 1, “A” should be changed to --The-- because the claim depends from Claim 15.

At Claim 17, lines 1-2, “the anti-bacterial peptide derived from the Diptera insect” lacks proper antecedent basis because Claim 15 is not directed to an anti-bacterial peptide from a Diptera insect. It is recommended that Claim 17 be changed to depend from Claim 16.

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At Claim 17, line 2, "derived from" should be changed to --from-- because it is not known what it intended by "derived."

At Claim 20, line 3, "atacin, lysozyme, cecropin" is indefinite because it is unclear whether alternative language is intended. It is recommended that before "cecropin" --and-- be inserted.

Claim Rejections - 35 USC § 102

3. Claims 1 and 20 remain rejected and claim 12 is rejected under 35 U.S.C. 102(e) as being anticipated by Broekert *et al.* (U.S. Patent 5,538,525). This rejection is maintained for the reasons of record set forth in the last Official action mailed 3/31/98. Applicant's arguments filed 7/6/98 have been fully considered but they are not persuasive.

Amended Claim 12 is included in this rejection because the claim is now drawn to a plant with resistance to pathogenic bacteria comprising either "an expression cassette comprising a recombinant gene operably linked to a plant promoter" or "an expression cassette comprising a drug resistance gene operably linked to a plant promoter which is constitutively expressed." Either of these two alternatives read on transgenic plants transformed with almost any expression cassette and hence are clearly encompassed by the teaching of Broekert.

4. Claim 12 is rejected under 35 U.S.C. 102(e) as being anticipated by Jaynes *et al.* (U.S. Patent 5,597,945).

Amended Claim 12 is now drawn to a plant with resistance to pathogenic bacteria comprising either "an expression cassette comprising a recombinant gene operably linked to a

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plant promoter” or “an expression cassette comprising a drug resistance gene operably linked to a plant promoter which is constitutively expressed.” Either of these two alternatives read on transgenic plants transformed with almost any expression cassette and hence are clearly encompassed by the teaching of Jaynes.

Claim Rejections - 35 USC § 103

5. Claims 1-2, 12-13, 15, and 18-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,597,945). This rejection is maintained for the reasons of record set forth in the last Official action mailed 3/31/98. Applicant's arguments filed 7/6/98 have been fully considered but they are not persuasive.

6. Claims 1-2, 12-13, 15, and 18-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,597,945).

Response to Arguments

Applicant argues that neither of the cited patents teach whether the disclosed anti-microbial peptides would be useful at conferring resistance to fungal pathogens (response, p. 6). Examiner responds that claims 12-13 are directed to plants with resistance to pathogenic bacteria and claims 18-19 are directed to expression cassettes and expression vectors, and hence Applicant's argument does not relate to said claims. However, Examiner notes that Broekert discusses transformed plants with enhanced disease resistance generally, which includes resistance

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to both fungal and bacterial pathogens (see abstract, col. 4, Examples 24-25). Also, Jaynes clearly discloses transgenic plants with resistance to bacteria and fungi (see Examples 11-15).

Applicant also asserts that the claims have been amended to specifically exclude the three peptides disclosed in the Jaynes reference (response, p. 7). Examiner responds that amendment of the claims does not overcome the rejection based on the Broekaert reference. Also amended Claim 12 reads on both of the prior art references. Furthermore, amendment of the claims to exclude the peptides of the Jaynes reference does not overcome the obviousness rejection based on the Jaynes reference, in view of the broad scope of the pending claims. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to substitute another gene encoding an anti-microbial peptide, especially a lytic peptide, for the genes encoding lysozyme, atacin and cecropin disclosed by Jaynes, because anti-microbial genes are functional equivalents, and it would have been obvious to substitute one functional equivalent with another. The teachings of Jaynes clearly are drawn broadly to anti-microbial genes generally, and Jaynes has contemplated the substitution of many different anti-microbial genes in the invention (see col. 7, for example). One would have had a reasonable expectation of success given the success of Jaynes.

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Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Douglas Robinson, can be reached at (703) 308-2897. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Amy J. Nelson, Ph.D.

August 4, 1998



Douglas W. Robinson
Supervisory Patent Examiner
Technology Center 1600